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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------------|------------------|
| 10/721,892 | 11/26/2003 | Mathias Alterman | E072.1010.1 | 5982 |
| 7590 WOMBLE CARYLE Post Office Box 7037 Atlanta, GA 30357-0037 | 03/12/2007 | | EXAMINER STOCKTON, LAURA LYNNE | |
| | | | ART UNIT 1626 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 03/12/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|--------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/721,892 | ALTERMAN ET AL. |
| | Examiner | Art Unit |
| | Laura L. Stockton, Ph.D. | 1626 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 and 32-42 is/are pending in the application.
 - 4a) Of the above claim(s) 2-4, 6-8 and 36-41 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 5, 9-17, 19-27, 32-35 and 42 is/are rejected.
- 7) Claim(s) 18 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/26/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

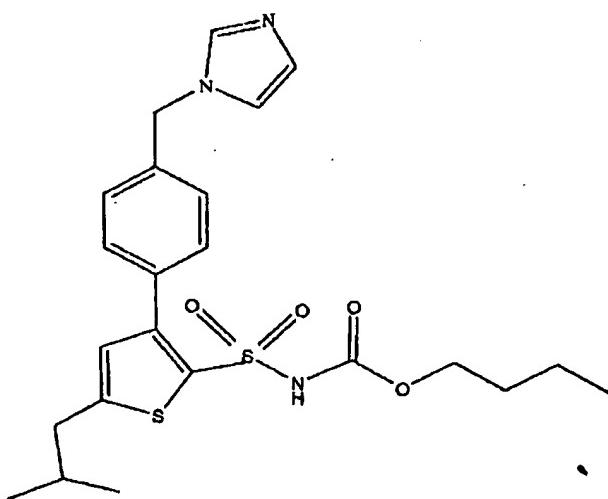
Claims 1-27 and 32-42 are pending in the application.

Election/Restrictions

Applicants' election with traverse of IV (claims 1, 5, 9-27 and 32-35), and the species found on page 34, lines 12-13 (reproduced below) in the reply filed on May 17, 2006 was acknowledged in the previous Office Action.

Example 1

N-Butyloxycarbonyl-3-(4-imidazol-1-ylmethylphenyl)-5-iso-butythiophene-2-sulfonamide



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At the request of Applicant, the restriction of Groups I through V has been considered but the inventions in Groups I-III and V are patentably distinct inventions from the elected invention of Group IV (directed to imidazole compounds). Applicant has not argued otherwise. The Examiner did indicate in the previous Office Action that Applicant can suggest the combining of one or two other final product groups (page 5, lines 16-19). However, Applicant has proposed combining four other final product groups with the elected group. As stated in the previous Office Action, the Examiner is not afforded the time per case to examine four additional inventions. The requirement was deemed proper and therefore made FINAL.

Subject matter not embraced by elected Group IV and Claims 2-4, 6-8 and 36-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being

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drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on May 17, 2006..

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in the United Kingdom on May 31, 2001, September 7, 2001 and January 26, 2002. It is noted, however, that applicant has not filed certified copies of the United Kingdom applications as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on December 26, 2006.

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Rejections and objections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections and objections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 42, since Z_1 can only represent "-S-", provisos (b) and (c) and the if then scenario under the definition of R^4 makes the claim confusing and unclear. Therefore, claim 42 is indefinite.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 9-17, 19-27 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleemann et al. {U.S. Pat. 6,335,451} in view of Corbier et al. {U.S. Pat. 5,807,878}.

Determination of the scope and content of the prior art (MPEP***§2141.01)***

Applicant claims imidazole compounds. Kleemann et al. teach imidazole compounds that are structurally similar to the instant claimed compounds and are useful in treating, for example, angina pectoris. See in Kleemann et al., for example, formula I in column 1 wherein R1, R2, R3, R4 and R5 each represent is hydrogen (columns 1-2; columns 14-20; and especially

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the particularly preferred compounds starting at column 4, line 15).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of Kleemann et al. and the compounds instantly claimed is that Kleemann et al. do not teach the substituents defined by the instant R⁴ variable. Kleeman et al. teach a sulfonylcyanamide group instead of the various substituents defined by the instant R⁴ variable such as -S(O)₂N(H)C(O)R⁶, -N(H)S(O)₂N(H)C(O)R⁷, -N(H)C(O)N(H)S(O)₂R⁷, etc.

Finding of prima facie obviousness--rational and motivation (MPEP

§2142-2413)

However, Corbier et al., also teach imidazole compounds that are useful in treating angina pectoris (column 30, lines 10-26) and that are structurally similar to the compounds of Kleemann et al. (column 1).

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Corbier et al. teach the interchangeability of sulfonylcyanamide group (column 4, last substituent on line 4) and a substituent embraced by the instant R⁴ variable (i.e., column 3, last substituent on line 67; column 4, first substituent on line 1; column 4, first substituent on line 4; and R₁₄ is defined in column 4, lines 13-46).

One skilled in the art would thus be motivated to prepare products embraced by Kleemann et al., especially in view of the teachings of Corbier et al., to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, angina pectoris. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

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Response to Arguments

Applicant's arguments filed December 26, 2006 have been fully considered but they are not persuasive.

Applicant argues that: (1) Corbier et al. do not teach the interchangeability of a sulfonylcyanamide group and the instant R⁴ variable but provides a long list of substituents that can be present; (2) Kleeman et al. distinguish their compounds from the prior art by the sulfonylcyanamide group, which must be present, and by the biological activity; and (3) Kleeman et al. teach away from the substitution of a sulfonylcyanamide group.

All of Applicant's arguments have been considered but have not been found persuasive. Corbier et al. do teach the interchangeability of a sulfonylcyanamide group and a group at the instant R⁴ variable position. See in Corbier et al., for example, column 4, last substituent on line 4; and substituents embraced by the instant R⁴ variable found in column 3, last substituent

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on line 67; column 4, first substituent on line 1; column 4, first substituent on line 4; and R₁₄ is defined in column 4, lines 13-46. Further, Corbier et al. prepare compounds having such substituents. See in Corbier et al., for example, the compound in column 16, lines 4-6.

In column 14, lines 46-50, Kleemann et al. do discuss the difference in the prior art compounds and their compounds as argued by Applicant. However, Kleemann et al.'s comments are not considered a negative teaching as argued by Applicant. Kleemann et al. recognize that it is well known in the art that the imidazole compounds are angiotensin II receptor antagonists. In fact, Kleemann et al. list WO 95/23791 (column 14, line 51), which is the WIPO equivalent of the above applied Corbier et al. reference. For all the reasons given above, the instant claimed inventions would have been suggested to one skilled in the art and

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therefore, would have been obvious to one skilled in the art.

Allowable Subject Matter

The elected species, found on page 34 on lines 12-13 of the instant specification, is allowable over the art of record.

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if: (1) rewritten in independent form including all of the limitations of the base claim and any intervening claims; and (2) directed solely toward the subject matter of elected Group IV.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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This application contains subject matter not embraced by elected Group IV and Claims 2-4, 6-8 and 36-41 drawn to invention nonelected with traverse in the reply filed on May 17, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-069.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

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automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

March 8, 2007